HED DOC. NO. 013673

August 12, 1999

MEMORANDUM

SUBJECT: ***PROPARGITE*** **-** Report of the FQPA Safety Factor Committee

FROM: Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)

THROUGH: Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

TO: Thurston Morton, Risk Assessor
Reregistration Branch 4
Health Effects Division (7509C)

PC Code: 097601

The FQPA Safety Factor Committee met on August 9, 1999 to evaluate the hazard and exposure data for propargite and recommended that the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be removed (1x) in assessing the risk posed by this chemical.

I. HAZARD ASSESSMENT

(*Memorandum:* S. Shallal to T. Morton dated June 22, 1999)

A. Adequacy of the Toxicology Database

The toxicology database for propargite is adequate according to the Subdivision F Guideline requirements for a food-use chemical.

B. Determination of Susceptibility

The data provided no indication of increased susceptibility in rats or rabbits from *in utero* and/or post natal exposure to propargite. In the prenatal developmental toxicity studies in rats, no developmental toxicity was observed at the limit dose, the highest dose tested. In the prenatal developmental toxicity studies in rabbits and in the two-generation reproduction study in rats, effects in the fetuses / offspring were observed at doses higher than those producing maternal / parental effects.

C. Determination of Developmental Neurotoxicity Study

The HIARC determined that a developmental neurotoxicity study with propargite in rats is not required.

II. EXPOSURE ASSESSMENTS

A. Dietary (Food) Exposure Considerations

(*Correspondence:* J. Stokes and T. Morton to B. Tarplee dated July 29, 1999)

Permanent tolerances are established for residues, propargite, in or on various plant and animal commodities at levels ranging from 0.1 to 50 ppm. Many of these commodities are considered to be highly consumed by infants and children, such as apples, beans, oranges, pears, peaches, and milk. Residues are not systemic, however have been found to transfer to meat/milk for which tolerances are established. Codex MRLs for propargite range from 0.1 to 80 ppm.

The HED Metabolism Assessment Review Committee (MARC) determined that parent propargite is the residue of concern for the tolerance expression and for dietary risk assessment (including drinking water). Additionally, the MARC requested metabolism information concerning the 2-propynyl sulfite side-chain contained in the parent compound (*Memorandum*: N. Dodd to G. Kramer dated June 7, 1999). The FQPA SFC members concluded that the lack of this data (metabolism of the 2-propynyl sulfite side-chain) would not impact the safety factor recommendation since the toxicological effects of this compound would have been observed in the developmental and reproduction studies when the parent compound was administered.

Data sources for propargite include residue data from field trial studies for all registered crops, monitoring data from the USDA Pesticide Data Program for grapes, oranges, and sweet corn (1995-97), as well as a Market Basket Survey conducted by the registrant. A 1998 Qualitative Usage Analysis was provided to HED by the Biological and Economic Analysis Division which includes percent crop treated information for propargite on several commodities.

Dietary food exposure analyses were performed to estimate the acute and chronic dietary risk for propargite using the Dietary Exposure Evaluation Model (DEEM). DEEM combines pesticide residue data with food consumption data to estimate dietary (food only) exposure. Both the chronic and acute analyses are highly refined using anticipated residue estimates based on available monitoring data and field trials as well as percent crop treated information. The result is a more realistic estimate of the dietary exposure expected from the application of propargite to food commodities.

The Committee recognizes that further refinement to the dietary food exposure analyses may be required as the risk assessment is developed. Therefore, provided the final dietary food exposure assessment does not underestimate the potential risk for infants and children, the safety factor recommendations of this Committee stand.

B. Dietary (Drinking Water) Exposure Considerations
(*Correspondence:* G. Maske to B. Tarplee, dated July 29, 1999.)

The environmental fate database for propargite is adequate to characterize the potential for contamination of drinking water sources. These data indicate that propargite is moderately persistent and relatively immobile. Based on fate characteristics, propargite is not expected to reach ground water and surface waters.

Limited surface and ground water monitoring data are available for parent propargite from the USGS National Water Quality Assessment indicating low level detections. EFED screening level models (GENEEC and SCI-GROW) were used to calculate the estimated environmental concentrations (EECs) for surface and ground water.

Tier II (PRZM/EXAMS) was performed for surface water estimates because Tier I results exceeded certain aquatic exposure levels. In performing the Tier II assessment, several factors were considered in choosing the modeling scenario. These factors included maximum application rate, number of applications, interval between applications, irrigation system, and the vulnerability of the soil in the use area. Although the highest propargite application rate is for use on walnuts, the corn use scenario was used in modeling so that the potential for runoff would not be underestimated.

C. Residential Exposure Considerations
(*Correspondence:* T. Morton to B. Tarplee, dated August 2, 1999)

There are currently no registered residential uses for propargite.

III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

A. Recommendation of the Factor

The Committee recommended that the FQPA safety factor for protection of infants and children (as required by FQPA) be **removed (1x).**

B. Rationale for Removing the FQPA Safety Factor

The Committee concluded that the safety factor could be removed for propargite because:

1. The toxicology database is complete for FQPA assessment;

2. The toxicity data provide no indication of increased susceptibility of young rats or rabbits to propargite;

3. The HIARC determined that a developmental neurotoxicity study is not required;

4. The exposure assessments will not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of propargite; and

5. There are currently no residential (non-occupational) uses of propargite.